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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,361	06/20/2003	Jean-Marie Andrieu	1187-R-02	7112

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,361	ANDRIEU ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44 and 52-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44 and 52-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-43, 45-51 are cancelled. Claims 44 and 52-56 are pending and under examination.

Specification

2. The amendment filed 02/25/008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. 37 CRF 1.57 (c) provides that essential material may be incorporated by reference by only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. In the instant case, the incorporation by reference of essential materials requested by Applicant by referencing to a non-patent publication is improper.

Essential material is "Essential material " is material that is necessary to: (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112; (2)

Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 44 and 52-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant new matter rejection is directed to the addition of incorporation by reference language that has been added to the claims. In the instant case, until the incorporation by reference is perfected, a new matter rejection is necessary.

Claim Rejections - 35 USC § 102

5. The rejection of claims 43 and 46 is withdrawn in view of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Applicant's amendment to the claims via incorporation by reference, as noted above, has been noted. However, because the incorporation by reference is not in compliant with 37 CFR 1.57, the newly added language to the claims is not considered. The incorporated languages presented in the claims are withdrawn from consideration until the incorporation by reference is perfected. The following is a rejection of the claims as they were presented in the previous claims listing, minus a change in dependency.

Additionally, in view of the issues noted with Applicant's attempt to incorporate by reference, the declaration of Gougeon is rendered moot until the incorporated by reference is perfected.

8. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belardelli et al.[1]

Claim 44 is directed to the composition of claim 43, however, further

The claims are directed to a composition comprising dendritic cells pulsed with an inactivated human immunodeficiency virus (HIV), wherein the dendritic cells are obtained from a monocyte by plastic-adherence followed by culture with GM-CSF and

[1] Belardelli et al. U.S. PreGrant Patent No. 2003/0092177 A1, filed April 27, 2001.

IL-4 and a pharmaceutically acceptable carrier, requires that the virus be autologous and wherein the virus is chemically inactivated by 2,2'-dithiopyridine .

Belardelli et al. teaches composition comprising dendritic cells pulsed with an inactivated human immunodeficiency virus (HIV) and a pharmaceutically acceptable carrier. [Paragraphs 0066-0067 and 0071, in particular.] The dendritic cells used by Belardelli et al. were obtained from a monocyte by plastic-adherence followed by culture with GM-CSF and IL-4. Belardelli et al. uses AT-2, 2,2'-dithiopyridine, to chemically inactivate the virus. And Belardelli et al. uses autologous dendritic cells.

While the dendritic cells used by Belardelli et al. are autologous, it is not readily apparent if the virus used by Belardelli et al. is also autologous. It should be noted that Belardelli et al. uses the cells as an adjuvant, and the inactivated virus as an immunogen/antigen.

However, due to the many variability in the many type of HIV isolates and the ability of the virus to mutate, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to use autologous HIV. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to induce an immune response against the specific HIV isolate infecting the subject. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of autologous antigens is routinely practiced in the art.

It is noted that the claims require the composition to expands in vivo expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells;

however, MPEP § 2112 [R-3] (I) provides: [T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.

In the instant case, while it may be true that Applicant discovers that the claimed composition expands *in vivo* expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells; however, this discovery does not make the composition patentable over the composition of Belardelli et al. Belardelli et al. teaches a composition that is the same as instantly claimed. The composition of Belardelli et al. is the claimed composition. Hence, Belardelli et al. does not need to teach that the composition expands *in vivo* expression of virus-specific CD8+ T cells, and said virus-specific CD8+ cells kill HIV-infected cells to anticipate the claimed invention. The

composition of Belardelli et al. would have the same properties or functions recognized by Applicant.

9. Claims 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belardelli et al., as applied above to claim 44, in view of Lu et al.[2]

The claims require the composition to further comprise an adjuvant. The adjuvant is later limited to a protease inhibitor by claim 53, which depends on claim 52. The protease inhibitor is later limited indinavir by claim 54, which depends on claim 53. Claim 55, which depends on claim 54, later requires that the composition comprise a non-antiviral concentration of indinavir. And claim 56 limits the non-antiviral concentration to 10 nM.

The significance of Belardelli et al., as applied to claim 43, is provided above.

The composition of Belardelli et al. does not further comprise indinavir. However, Lu et al. teaches that indinavir direct up-regulate proliferation and down regulate apoptosis of T cells. [Paragraph bridging pages 247-248.]

Thus, would have been prima facie obvious for one of ordinary skill in the art to combine the teachings of Belardelli et al. and Lu et al. One of ordinary skill in the art would have been motivated to do so to optimize CTL response against HIV infection. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of a workable or optimal range is routinely practiced in the art.

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[2] Lu et al. HIV protease inhibitors restore impaired T-cell proliferative response in vivo and in vitro: a viral-suppression-independent mechanism. Blood, Jul 2000; Vol. 96, 250 - 258.

It is recognized that claims require the composition to contain non-antiviral concentration of indinavir, specifically 10 nM. In the instant, Lu et al. teaches that the extent in which indinavir up-regulate proliferation and down regulate apoptosis of T cells varies at different concentrations of indinavir. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any concentrations of indinavir, particularly since Lu et al. establishes that indinavir at various concentrations, ranging from .1nM to 1000 nM, stimulates direct up-regulate proliferation and down regulate apoptosis of T cells. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to determine the optimum concentration to optimize the proliferation of T cells. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of workable ranges or optimal value is routine practiced in the art.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 44 and 52-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/138171 in view of Belardelli et al. and Lu et al. This is a provisional obviousness-type double patenting rejection.

In response to this rejection, Applicant requested that the rejection be held in abeyance pending withdrawal of the other rejections.

Applicant's submission has been noted. Until the rejection is properly addressed, the rejection is maintained.

12. Claims 44 and 52-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 7 and 13 of copending Application No. 11/243094 in view of Belardelli et al. and Lu et al. This is a provisional obviousness-type double patenting rejection.

In response to this rejection, Applicant requested that the rejection be held in abeyance pending withdrawal of the other rejections.

Applicant's submission has been noted. Until the rejection is properly addressed, the rejection is maintained.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Primary Examiner, Art Unit 1648

/E. L./

Search Notes (continued)

Application/Control No.	Applicant(s)/Patent under Reexamination
10/600,361	ANDRIEU ET AL.
Examiner	**Art Unit**
Emily Le	1648

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
Updated previous search	10/12/2007	E.LE
USPAT, USPGPUB, DERWENT, EPO, JPO Medline		
Keywords: IL-4 GM-CSF HIV Pulsed Dendritic		
Class/subclass searched in text.		
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